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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,955	02/28/2001	Reld W. Von Borstel	1331-334	3848

7590 11/23/2005

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EXAMINER

LEWIS, PATRICK T

ART UNIT PAPER NUMBER

1623

DATE MAILED: 11/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/763,955

Applicant(s)

VON BORSTEL, RELD W.

Examiner

Patrick T. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-59 and 62-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-59 and 62-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10072005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 7, 2005 has been entered.

Election/Restrictions

2. Applicant's election with traverse of Group I in the reply filed on July 21, 2003 is acknowledged. The requirement was made FINAL in the Office Action dated September 9, 2004.

Applicant's Response Dated October 7, 2005

3. Claims 48-59 and 62-68 are pending. An action on the merits of claims 48-59 and 62-68 is contained herein below.

4. The provisional rejection of claims 54-59 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 31-32 and 38-41 of copending Application No. 09/930,494 is maintained for the reasons of record as set forth in the Office Action dated September 9, 2004.

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5. The rejection of claims 48-59 under 35 U.S.C. 112, second paragraph, has been withdrawn in view of applicant's arguments dated October 7, 2005.

6. The rejection of claims 48-59 and 62-68 under 35 U.S.C. 103(a) as being unpatentable over Page et al. Proc. Natl. Acad. Sci. USA, 1997, Vol. 94, pages 11601-11606 (Page) in combination with von Borstel et al. US 6,316,426 B1 (von Borstel) is maintained for the reasons of record as set forth in the Office Action dated September 9, 2004.

Rejections of Record Set Forth in the Office Action Dated September 9, 2004

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 54-59 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 31-32 and 38-41 of copending Application No. 09/930,494.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Applicant has failed to set forth arguments as to why the provisional rejection is improper.

10. Claims 48-59 and 62-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Page et al. Proc. Natl. Acad. Sci. USA, 1997, Vol. 94, pages 11601-11606 (Page) in combination with von Borstel et al. US 6,316,426 B1 (von Borstel).

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11. Applicant's arguments filed October 7, 2005 have been fully considered but they are not persuasive. Applicant argues that overlapping symptoms are insufficient to establish a prima facie case of obviousness because it is well recognized that unrelated diseases can have overlapping symptoms.

The examiner respectfully disagrees with applicant's assessment of the instant rejection. Applicant's attention is directed to column 2 on page 11601 of Page wherein the population treated is characterized. "All patients were markedly delayed in their developmental milestones, especially language. All had seizures, ataxia, an awkward gait, and mildly impaired fine motor control. All four displayed an unusual behavioral phenotype that was characterized by extreme hyperactivity, distractability, a strange "delirious" quality to their affect, and abnormal social interaction. All four patients experienced frequent ear and sinus infections, but no consistent reason for immunodeficiency could be found." Applicant is further directed to page 1604 wherein Page describes the population after treatment. "At the higher dose, improvement in speech and behavior as well as greatly decreased seizure activity were noted. She began to pay more attention to her environment, focus better on tasks, and was not hyperactive. Interaction with others became more normal and appropriate for her age. Aggressive behavior ceased. Speech improved from short telegraphic sentences to longer, more complex, and age-appropriate expressions. Seizure activity decreased to the point that valproic acid (625 mg/day) was discontinued entirely, and the carbamazepine dose was decreased from 500 to 50 mg/day...Patient 2 was started on the same treatment regimen and showed similar improvement, with fewer seizures,

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decreased ataxia, improved speech and behavior, and improved performance on standardized tests of cognitive function.”

On page 22 of the instant specification applicant states, “As is demonstrated in the Examples, compounds and compositions of the invention are useful for treatment of a very broad spectrum of signs and symptoms in mitochondrial diseases with different underlying molecular pathologies. Improvements observed in these and additional patients include but are not limited to reduction of frequency and severity of seizures, migraines, and stroke-like episodes, improvement of weight gain in children with “failure to thrive”, amelioration of renal tubular acidosis with concurrent reduction in the need for supplementary bicarbonate, improvement of muscular strength, improvement of speech acquisition, improvement of ataxia, reduction of the frequency and severity of sinus and ear infections, improvement of memory, and amelioration of symptoms of autonomic and peripheral neuropathy. The improvements observed in a broad variety of symptoms which were basically nonresponsive to other forms of metabolic support...”

The population treated by the method of Page is the same or, at the very least, substantially overlaps the population treated by the instant method. The examiner maintains that applicant has merely found a new property of the instant uridine compounds (pyrimidine nucleotide precursors) and such a discovery does not constitute a new use. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. In construing process claims and references, it is the identity of manipulative operations which leads to finding of obviousness. In the instant case, it

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does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure.

Von Borstel teaches that the delivery of exogenous uridine or cytidine to animal tissue can be advantageously accomplished by administering to the animal an effective amount of one or more acyl derivatives. The acyl substituents can be selected to increase lipophilicity of the nucleoside, thus improving its transport from the gastrointestinal tract into the bloodstream. The teaching of von Borstel in combination with Page renders the use of acylated uridine compounds obvious.

Conclusion

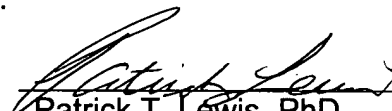
12. Claims 48-59 and 62-68 are pending. Claims 48-59 and 62-68 are rejected. No claims are allowed.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday 10 am to 3 pm (Maxi Flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Patrick T. Lewis, PhD
Examiner
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